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UNIVERSITY of LOUISVILLE  
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September 6, 2002

U.S. Food & Drug Administration  
Dockets Management Branch  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

(301) 827-6860

<http://www.fda.gov/opacom/backgrounders/html>

Dear Sirs:

*Public Comments on Packaging and Labeling Guidance for  
Manufacturers of Dental Amalgam and Other Dental Products*

As a research investigator and university teacher of dental materials, including dental amalgam, I see an **urgent need for proper labeling of all dental products** for transfer directly to patient records.

There are two major problems in the way dentists use modern clinical materials: a) unit dose products are **rarely labeled** directly to show what they are, *e.g.*, dental amalgam prepackaged capsules; and b) dentists usually **don't record the brand names** of the products they use in the patient record. Sketchy notes often doom legal cases because of their brevity or imprecision. If the brand name of the dental product were not in the written record and an incident were to occur some months or years in the future, it would be nearly impossible to go back to document the specific product that was used for the patient with certainty, enough to satisfy a plaintiff's litigator and a jury.

Both problems could be solved if manufacturers voluntarily a) placed a **peelable identification label** on each unit-dose capsule or container, and b) supplied a roll of peelable labels with all other multidose products that are dispensed from tubes or other forms of packaging. The dentist or staff member would simply peel off the label and place it into the patient's written record, permanently documenting the actual products used during treatment and lessen the requirements for handwritten details. This would also include dental products such as impression materials, which occasionally are trapped in oral tissues.

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Similar to the ongoing Identaloy labeling program for casting alloys and stickers used for some dental implants, the labels would contain: a) the manufacturer's name and logo, b)

product name and logo, c) ISO material type, d) ADA Seal as appropriate, e) composition, f) hazardous elements if any, g) packaging date and h) expiration date. Anesthetic carpules already have small labels containing this information, which should also be made peelable. The procedure lends itself to barcode labeling as well.

Such labeling would fulfill the **patient's right-to-know**, and satisfy **forensic requirements**. It would constitute free advertising and permanent documentation for manufacturers of name-brand materials, distinguishing them from me-too, no-name, or cut-rate products.

The dental profession must be accountable for the materials and products it uses, just as hospitals and pharmacies establish a paper trail for every drug they dispense. This accountability should be our **Standard of Care**. Dental patients deserve no less. It is time for the US Food & Drug Administration to correct the packaging and labeling guidelines for all dental products.

A recent Letter-to-the-Editor on this subject was published in the May 2002 issue of the *Journal of the American Dental Association* (133:548-50) explaining my views.

Sincerely,

A handwritten signature in black ink, appearing to read 'Lawrence Gettleman', written in a cursive style.

Lawrence Gettleman, DMD, MSD  
Professor of Prosthodontics & Biomaterials

LG/es

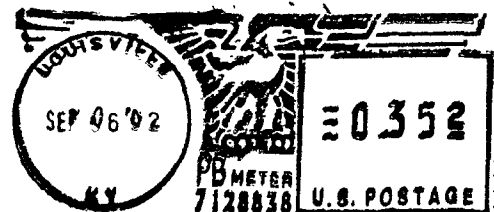
Dr. L. Gettleman

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